JUDGE MARRERO 10 CV 4207

IN THE UNITED STATES DISTRICT COURT
FOR THE SOURTHERN DISTRICT OF NEW YORK

ANN SANTOS	§	
	§	
Plaintiff	§	
	§	
vs.	§	**CIVIL ACTION NO. _____**
	§	
PFIZER, INC., PARKE-DAVIS,	§	**DEMAND FOR JURY TRIAL**
a division of Warner-Lambert Company	§	
WARNER-LAMBERT CO., and	§	
Warner-Lambert Company LLC,	§	
WARNER-LAMBERT COMPANY,	§	
WARNER-LAMBERT COMPANY LLC ,	§	
and PFIZER PHARMACEUTICALS,	§	
Defendants.	§	

COMPLAINT

Plaintiff, by and through the undersigned attorneys of record, and for the Complaint against the defendants, PFIZER, INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY and WARNER LAMBERT COMPANY LLC, and PFIZER PHARMACEUTICALS, states and alleges as follows:

I.

PRELIMINARY STATEMENT

1. This is an action to recover damages for personal injuries sustained by, ANN SANTOS, as the direct and proximate result of defendant's wrongful conduct in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Neurontin. Plaintiff's injuries and damages arose as a result of the use of neurontin drug products

manufactured, marketed, distributed and sold by Defendants and/or Defendants' representatives and placed in the stream of commerce by Defendants.

I.

PARTIES

2. Plaintiff, Ann Santos, is a citizen and resident of the State of Connecticut and was sold neurontin drug products in the State of Connecticut. Plaintiff's injuries were caused by Plaintiff's usage of Defendants' neurontin drug products. As more particularly plead below, aforementioned Plaintiff maintains that the drug is defectively designed, inadequately tested, dangerous to human health, and lacked proper warnings as to the dangers associated with its use.

3. That at all times on or before January 17, 2005, plaintiff was then and prior thereto, in generally good health, industrious and possessed all faculties.

4. That at all times on or before January 17, 2005, plaintiff was then and prior thereto, in generally good health, industrious and possessed all faculties.

5. Pfizer Inc., is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 235 East 42nd Street, New York, NY10017-5755.

6. Pfizer Inc.'s agent for service of process is CT Corporation System, 208 So. LaSalle Street, Suite 814, Chicago, IL, 60604.

7. Pfizer Inc., all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing neurontin drug products in the stream of commerce for use by the public, including plaintiff.

8. Parke-Davis, a division of Warner Lambert, is a corporation organized under the laws of the State of Michigan having its headquarters and principal place of business at 201 Taber Road, Morris Plains, New Jersey, 07950.

9. Parke-Davis, a Division of Warner Lambert, all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing neurontin drug products in the stream of commerce for use by the public, including plaintiff.

10. Defendant Warner-Lambert Company, is a Delaware corporation with its headquarters at 201 Tabor Road, Morris Plains, New Jersey 07950.

11. Warner-Lambert Company's agent for service of process is CT Corporation System, 208 So. LaSalle Street, Suite 814, Chicago, IL, 60604.

12. Defendant Warner-Lambert Company, at all times material hereto has and continues to do business in this state

13. At all times relevant herein, Warner-Lambert Company, was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing neurontin drug products, for use by the mainstream public, including plaintiff.

14. Defendant Warner-Lambert LLC, is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, NY 10017-5755.

15. Warner-Lambert LLC's agent for service of process is CT Corporation System, 208 So. LaSalle Street, Suite 814, Chicago, IL, 60604.

16. Defendant Warner-Lambert LLC, at all times material hereto has and continues to do business in the state.

17. At all times relevant herein, Warner-Lambert LLC, was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing neurontin drug products, for use by the mainstream public, including plaintiff.

18. That at all times hereafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, was and still is a foreign limited liability company authorized to do business in the State of New York.

19. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., is the sole shareholder and member of the defendant, WARNER-LAMBERT COMPANY LLC.

20. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a division of the defendant, WARNER-LAMBERT COMPANY LLC.

21. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is a subsidiary of the defendant, WARNER-LAMBERT COMPANY, LLC.

22. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a division of the defendant, PFIZER INC.

23. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a subsidiary of the defendant, PFIZER, INC.

24. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is a successor in interest to the defendant, PARKE-DAVIS.

25. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a division of the defendant, PFIZER, INC.

26. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to the defendant, PARKE-DAVIS.

27. That on a date prior to January 17, 2005, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

28. That on a date prior to January 17, 2005, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY.

29. That on a date prior to January 17, 2005, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY, consolidated with each other.

30. That on or about January 17, 2005, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

31. That on or about January 17, 2005, the defendant, WARNER-LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

32. That on or about January 17, 2005, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

33. That on or about January 17, 2005, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

34. That on or about January 17, 2005, the defendant, PARKE-DAVIS, merged with the defendant, WARNER-LAMBERT COMPANY LLC, and the defendant, PARKE-DAVIS, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

35. That on or prior to January 17, 2005, the defendant, PARKE-DAVIS, and the defendant, WARNER-LAMBERT COMPANY LLC, consolidated with each other.

36. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY LLC, is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

37. That on or prior to January 17, 2005, the defendant, WARNER-LAMBERT COMPANY LLC, assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY.

38. That on or prior to January 17, 2005, the defendant, WARNER LAMBERT COMPANY LLC, expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

39. That on or prior to January 17, 2005, the defendant, WARNER-LAMBERT COMPANY LLC, impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

40. That on or prior to January 17, 2005, the defendant, WARNER-LAMBERT COMPANY, and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

41. That on or prior to January 17, 2005, the defendant, WARNER-LAMBERT COMPANY, merged with the defendant, WARNER-LAMBERT COMPANY LLC, and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, WARNER-LAMBERT COMPANY LLC.

42. That on or prior to January 17, 2005, the defendant, WARNER-LAMBERT COMPANY, and the defendant, WARNER LAMBERT COMPANY LLC, consolidated with each other.

43. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., is a successor in interest to the defendant, PARKE-DAVIS.

44. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, inc., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY.

45. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., is a successor in interest to the defendant, WARNER-LAMBERT COMPANY LLC.

46. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., assumed the assets and liabilities of the defendant, PARKE-DAVIS.

47. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., expressly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

48. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., impliedly assumed all liabilities and obligations of the defendant, PARKE-DAVIS.

49. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., assumed the assets and liabilities of the defendant WARNER-LAMBERT COMPANY.

50. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

51. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., impliedly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY.

52. That on or prior to January 17, 2005, the defendant, PFIZER, INC., assumed the assets and liabilities of the defendant, WARNER-LAMBERT COMPANY LLC.

53. That on or prior to January 17, 2005, the defendant, PFIZER, INC., expressly assumed all liabilities and obligations of the defendant, WARNER-LAMBERT COMPANY LLC.

54. That on or prior to January 17, 2005, the defendant, PFIZER, INC., impliedly assumed all liabilities and obligations of the defendant WARNER-LAMBERT COMPANY LLC.

55. That on a date prior to January 17, 2005, the defendant, PFIZER INC., and the defendant, PARKE-DAVIS, merged with each other.

56. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., and the defendant, WARNER-LAMBERT COMPANY, merged with each other.

57. That on or before January 17, 2005, the defendant, PFIZER, INC., and the defendant, WARNER-LAMBERT COMPANY LLC, merged with each other.

58. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., and the defendant, PARKE-DAVIS, merged with each other and the defendant, PARKE-DAVIS, became a part of the defendant, PFIZER, INC.

59. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., and the defendant, WARNER-LAMBERT COMPANY, became a part of the defendant, PFIZER, INC.

60. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., and the defendant, WARNER-LAMBERT COMPANY LLC, became a part of the defendant, PFIZER, INC.

61. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., and the defendant, PARKE-DAVIS, consolidated with each other.

62. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., and the defendant, WARNER-LAMBERT COMPANY consolidated with each other.

63. That at all relevant times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., has its principal place of business in the State of New York.

64. In the year 2000, the defendant, PFIZER, INC., acquired the defendant, WARNER-LAMBERT COMPANY, and as a result of that acquisition, the defendant, PFIZER, INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, WARNER-LAMBERT COMPANY, which occurred prior to such acquisition.

65. In the year 2000, the defendant, PFIZER, INC, acquired the defendant, PARKE-DAVIS, a division of Warner-Lambert Company, and as the result of that acquisition, the defendant, PFIZER, INC., is responsible for all liabilities resulting from the acts or omissions of the defendant, PARKE-DAVIS, which occurred prior to such acquisition.

66. On or prior to December 31, 2002, defendant, PFIZER, INC., acquired the defendant, WARNER-LAMBERT COMPANY LLC, and pursuant to the terms of and conditions of that acquisition, the defendant, PFIZER, INC., is responsible for all acts and omissions of the defendant, WARNER-LAMBERT COMPANY, LLC, occurring prior to such acquisition.

67. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., presently markets and sells the drug Neurontin.

68. That on a date prior to January 17, 2005, the defendant, PFIZER, INC., marketed and sold the drug Neurontin.

69. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., is engaged in the business of designing, manufacturing, advertising, marketing and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

70. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., committed a tortuous act inside the State of New York, which caused injury to plaintiff inside the State of New York.

71. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

72. That at all times hereinafter mentioned, upon information and belief, the defendant, PFIZER, INC., expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

73. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, presently markets and sells the drug Neurontin.

74. That on a date prior to January 17, 2005, the defendant, PARKE-DAVIS, marketed and sold the drug Neurontin.

75. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

76. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, committed a tortuous act, which caused injury to plaintiff.

77. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, regularly does and solicits business and engages in a persistent courts of conduct in the State of New York, deriving substantial revenue from

goods and products consumed in New York and throughout the nation, including the State of Connecticut.

78. That at all times hereinafter mentioned, upon information and belief, the defendant, PARKE-DAVIS, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

79. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LABMERT COMPANY, presently markets and sells the drug Neurontin.

80. That on a date prior to January 17, 2005, the defendant, WARNER-LAMBERT COMPANY, marketed and sold the drug Neurontin.

81. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

82. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, committed a tortuous act, which caused injury to plaintiff.

83. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products sold inside and outside the State of New York.

84. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

85. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, LLC, presently markets and sells the drug Neurontin.

86. That on a date prior to January 17, 2005, the defendant, WARNER-LAMBERT COMPANY, LLC, marketed and sold the drug Neurontin.

87. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, LLC is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Neurontin, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

88. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, LLC, committed a tortuous act, which caused injury to plaintiff.

89. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, LLC, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products sold inside and outside the State of New York.

90. That at all times hereinafter mentioned, upon information and belief, the defendant, WARNER-LAMBERT COMPANY, LLC, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

91. Defendant, Pfizer Pharmaceuticals, Inc., is a Delaware corporation with its headquarters in New York.

92. Defendant Pfizer Pharmaceuticals, Inc., at all times material hereto has and continues to do business in the State of Illinois.

93. At all times relevant herein, Pfizer Pharmaceuticals, Inc., was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing neurontin drug products, for use by the mainstream public, including plaintiff.

94. That on a date prior to January 17, 2005, to the defendant, WARNER-LAMBERT COMPANY, assumed the assets and liabilities of the defendant, PARKE-DAVIS.

95. Defendants at all times relevant advertised, marketed, promoted, sold and/or distributed neurontin drug products throughout this state and throughout interstate commerce.

96. At all times relevant herein, Defendants were in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing neurontin drug products for use by the mainstream public, including Plaintiff.

II.

JURISDICTION AND VENUE

97. Jurisdiction exists as against the defendants, PFIZER, PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC (hereinafter "PARKE-DAVIS"), WARNER-LAMBERT COMPANY and WARNER-LAMBERT COMPANY LLC, pursuant to:

(a) 28 U.S.C. Section 1332, in that the plaintiff, is a citizen and resident of Connecticut; the defendant, PFIZER, INC., is incorporated in business in the State of Delaware, and maintains its principal place of business in the State of New York, the defendant, PARKE-DAVIS, is incorporated in the State of Michigan, and maintains its principal place of business in the State of New Jersey, the defendant, WARNER-LAMBERT COMPANY LLC, is a limited liability organized under the laws of the State of Delaware, whose sole shareholder and member is the defendant, PFIZER, INC.; the

amount in controversy exceeds the sum of $75,000.00, and there is complete diversity of citizenship between plaintiff and defendant.

(b) Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over the Defendants, because Defendants are present in this state such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

(c) This Court has personal jurisdiction over the Defendants, pursuant to, and consistent with, the Constitutional requirements of Due Process in that the Defendants acting through agents or apparent agents, committed one or more of the following:

i. Defendants transacted business in this state;

ii. Defendants owned, used or possessed real estate situated in this state;

iii. Defendants made or performed a contract or promise substantially connected within this state;

iv. Defendants do business in and within this state; and;

v. Requiring Defendants to litigate this claim in this state does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

(d) Defendants marketed, promoted, and sold neurontin drug products concerned in this litigation throughout the United States. Additionally, the Plaintiff herein suffered injury from Defendants' neurontin drug products in this state. Accordingly venue is proper.

III.

STATEMENT OF FACTS

A. Regulatory History

98. Pursuant to the Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. §§ 301 et seq., new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.SC. §355 (a) and (d).

99. However, the FDCA does not prevent doctors from prescribing a drug approved for a particular use for other users that are different than those approved by the FDA ("off-label" usage).

100. Nonetheless, even though physicians may prescribe drugs for "off-label" usage, the FDCA prohibits drug manufacturers themselves from marketing and promoting a drug fro a use that the FDA has not approved. 21 U.S.C. § 331(d).

101. A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about unapproved uses or if the manufacturer engages directly or indirectly in marketing or promoting the drug for unapproved uses.

102. Instead, if a manufacturer desires to market and promote the drug for new uses in addition to those already approved, the materials on off-label usage must meet certain stringent requirements and the manufacturer must re-submit the drug to the FDA approval process for the proposed new use.

103. The above-described statutory and regulatory system and process is designed to protect the public, including plaintiff, from the dangers arising from drugs which, although approved for a certain specific condition, disease or purpose, could cause injury and harm if used for an "off-label" purpose without adequate study and testing of the drug for such "off-label" usage, and to protect the public, including plaintiffs' decedent herein, from the dangers arising from deceptive, misleading, and inaccurate advertising, marketing, and promotional materials, issued directly or indirectly by the manufacturer to encourage the "off-label" usage of the drug without adequate testing and study of the drug for such "off-label" usage.

104. PARKE-DAVIS, now owned by PFIZER, INC., applied for, and in December 1993, received FDA approval to market and sell Neurontion solely for "adjunctive therapy" in the treatment of certain types of seizures in adult patients suffering from epilepsy, and the FDA approved labeling of Neurontin for that purpose and stated that the drug is only effective at 900 to 1800 milligrams per day.

105. At no time prior to plaintiff being prescribed Neurontin, did defendants receive FDA approval for any other use of Neurontin except for the above-described treatment of epilepsy or for higher dosages for any purpose, and the FDA never approved the usage of Neurontin at any dosage for the treatment of chronic pain and depression.

106. Commencing in 1995, defendants, as the manufacturer of Neurontin, began to directly and indirectly advertise, market and promote Neurontin for additional "off-label" uses for which FDA approval had not been obtained, including treatment for chronic pain and depression and at higher dosages than had been tested and approved, in violation of the above-described statutory and regulatory system and process, including the FDCA, which prohibits manufacturers from directly or indirectly advertising, marketing, and promoting a drug for "off-label" usage, and instead requires that the manufacturer resubmit the drug to the FDA testing and approval process for the proposed new use and that the materials issued by the manufacturer relating to the proposed new use meet certain stringent requirements.

107. Defendants, as the manufacturer of Neurontin, directly and indirectly advertised, marketed and promoted Neurontin for the treatment of chronic pain and depression and encouraged that higher dosages than those tested be prescribed, even though defendant knew or should have known that there were not adequate tests and studies establishing and confirming that Neurontin was safe and effective for the treatment of chronic pain and depression, and even though defendants knew or should have known that there was no adequate studies showing that Neurontin was safe when prescribed at dosages higher than those approved by the FDA.

108. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of chronic pain and depression even though defendants knew or should have known that Neurontin caused many symptoms or related risk factors associated with suicidal behavior by persons suffering from chronic pain and depression.

109. At all times hereinafter mentioned, upon information and belief, defendants marketed and promoted Neurontin for the treatment of chronic pain and depression even though defendants knew or should have known that Neurontin had no effect in relieving or correcting the symptoms or cause of chronic pain and depression.

110. Defendants' conduct in promoting "off-label" uses of Neurontin for treatment of chronic pain and depression constituted a wanton, callous and reckless disregard of the safety of the of the public, and in particular of persons suffering from chronic pain and depression.

111. In promoting "off-label uses of Neurontin, and at higher dosages than approved by the FDA, including treatment of chronic pain and depression, defendants acted without regard to the potential danger and harm to persons for whom the drug was prescribed for the treatment of chronic pain and depression.

112. Defendants actively distributed, sold and placed Neurontin into the stream of commerce and directly and indirectly advertised, marketed and promoted Neurontin as being safe and effective for the treatment of chronic pain and depression and in dosages higher than those approved by the FDA, even though the only approved use of Neurontin at that time was a "adjunctive therapy" for the treatment of epilepsy and even though the FDA had specified a maximum recommended dosage.

113. Neurontin is not reasonably safe and effective for the treatment of persons suffering from chronic pain and depression, and is not reasonably safe when consumed in higher dosages than those approved by the FDA, and defendants' conduct of illegally advertising, marketing and promoting Neurontin for this "off-label" uses was unlawful, deceptive and misleading and was violative of the FDCA.